

## **REMARKS**

Claims 1-49 were previously canceled. Claims 50, and 51 are currently amended. Claims 55- 89 are newly presented. Claims 50-89 are currently pending. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following Remarks.

### **I. INFORMATION DISCLOSURE STATEMENT**

Applicant acknowledges, with appreciation, the Examiner's indication that the references submitted in the Information Disclosure Statements filed June 17, 2005 and August 22, 2005 have been considered.

Applicant notes, however, that they have not received an acknowledgement of review of references for the Information Disclosure Statements filed on September 9, 2003, November 3, 2004, March 8, 2005, and July 28, 2006. Applicant looks forward to the Examiner's indication that those references have been considered.

### **II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102**

In order for Applicant's claims to lack novelty under 35 U.S.C. § 102 (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. A prior art reference anticipates a claim *only if* the reference discloses, either expressly or inherently, every limitation of the claim.

The Patent Examiner bears the burden of demonstrating that Applicant's invention is anticipated by the reference relied on in the Examiner's reasons for rejection.

For the following reasons, Applicant respectfully assert that the Examiner has not met this burden.

#### **A. Claims 50-52, and 54 have been rejected under 35 U.S.C. § 102(b) over Fitz (Re. 36,758).**

The Examiner has rejected claims 50-52, and 54 under 35 U.S.C. § 102(b) as being anticipated by Re. 36,758 to Fitz ("Fitz"). The Examiner asserts that "Fitz discloses a prosthesis for the replacement of at least a portion of the bone of a facet located on a mammalian vertebra comprising; a surface that articulates with another facet surface; a fixation portion that is

configured for implantation in an interior bone space of said vertebra, said surface being connected to said fixation portion.” (See, Office Action dated August 10, 2006, p. 2)

Fitz discloses an artificial facet joint which is configured to be “place[d] over the tip of the articular process.” (Fitz, Col. 3, Ins. 8-10; and Fig. 3). Nothing in Fitz discloses a prosthesis with a fixation portion that is configured for implantation into an interior bone space of a mammalian vertebral body or a longitudinally-extending portion that is longer than a pedicle of the vertebra, as claimed by Applicant. Claim 50 and newly presented claims 68 and 78 include similar limitations and therefore are not anticipated by Fitz.

For the foregoing reasons, Applicant’s claim 50 is not anticipated by Fitz under 35 U.S.C. § 102(b), nor is newly presented claims 68 and 78. Therefore, Applicant requests that the Examiner withdraw his rejection of claim 50. Furthermore, claims 51, 52, and 54 depend directly or indirectly from claim 50 and include the limitations thereof. For the reasons provided with respect to claim 50, claims 51, 52, and 54 are not anticipated by Fitz under 35 U.S.C. § 102(b). Therefore, Applicant also requests that the rejection of claims 51, 52 and 54 under 35 U.S.C. § 102(b) be withdrawn as well.

**B. Claims 50-52, and 54 have been rejected under 35 U.S.C. § 102(b) over Vitale (U.S. Patent 5,683,466).**

The Examiner has further rejected claims 50-52, and 54 under 35 U.S.C. § 102(b) as being anticipated U.S. Patent No. 5,683,466 to Vitale (“Vitale”). The Examiner asserts that “Vitale discloses a prosthesis for the replacement of at least a portion of the articular surface of a bone comprising: a surface that articulates with another complimentary surface; a fixation portion that is configured for implantation in an interior bone space, said surface being connected to said fixation portion.” (See, Office Action dated August 10, 2006, p. 4).

Vitale discloses a metatarsal phalangeal articular surface replacement system. Nothing in Vitale discloses a prosthesis with a facet surface that articulates with a natural or artificial facet surface of an opposing vertebral body, a fixation portion that is configured for implantation into an interior bone space of a mammalian vertebral body or a longitudinally-extending portion that is longer than a pedicle of the vertebra, as claimed by Applicant.

Accordingly, Applicant’s claim 50 is not anticipated by Vitale under 35 U.S.C. § 102(b), nor are newly presented claims 68 and 78. Therefore, Applicant requests that the Examiner

withdraw his rejection of claim 50. Furthermore, claims 51, 52, and 54 depend directly or indirectly from claim 50 and include the limitations thereof. For the reasons provided with respect to claim 50, claims 51, 52, and 54 are not anticipated by Vitale under 35 U.S.C. § 102(b). Therefore, Applicant also requests that the rejection of claims 51, 52 and 54 under 35 U.S.C. § 102(b) be withdrawn as well.

**III. CLAIM 53 HAS BEEN REJECTED UNDER 35 U.S.C. § 103(A) OVER FITZ OR VITALE AS APPLIED TO CLAIM 50, AND FURTHER IN VIEW OF DAVIDSON (U.S. PATENT NO. 5,348,026) OR BOWMAN ET AL. (U.S. PATENT NO. 4,950,270)**

The Examiner has rejected Claim 53 under 35 U.S.C. § 103(a) as being unpatentable over Fitz or Vitale as applied to claim 50 above, and further in view of U.S. Patent No. 5,348,026 to Davidson ("Davidson") or U.S. Patent No. 4,950,270 to Bowman et al. ("Bowman et al."). The Examiner asserts that "Davidson and Bowman et al. teach the concept for coating an osteo-screw with a coating of osteoinductive substance to reduce the tendency for stress concentration and promote new tissue attachment." The Examiner further asserts that "to coat the screw of Fitz or Vitale with an osteoinductive material to reduce the likelihood of failure of the fixation of the implant would have been obvious to one with ordinary skill in the art from the teachings of Davidson or Bowman et al." (See, Office Action dated August 10, 2006, p. 5).

During patent examination the PTO bears the initial burden of supporting a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. Mere identification in the prior art of each element is insufficient to defeat patentability of the combined subject matter. There must also be some suggestion or motivation to modify the reference or to combine reference teachings. See MPEP § 2142. Thus, there must be some positive, concrete evidence which gives a logical reasoning which justifies a combination of references.

In practice, this requires that the Examiner explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious. Further, the factual inquiry of whether to combine references must be based on

the objective evidence of record. Failure to meet that burden is a basis for the Board to overturn the obviousness rejection. The Examiner cannot simply use conclusory statements to support the rejection. As the Federal Circuit has noted the motivation-suggestion-teaching requirement protects against the entry of hindsight into the obviousness analysis.

Applicant believes the Examiner has not met his burden under § 103 for the following reasons:

Claim 53 depends indirectly from claim 50 and includes the limitations thereof. As discussed above, neither Fitz nor Vitale disclose a fixation portion that is configured for implantation into an interior bone space of a mammalian vertebral body or a longitudinally-extending portion that is longer than a pedicle of the vertebra as claimed by Applicant. Davidson discloses an osteoconductive bone screw and Bowman discloses a self-tapping bone screw. Neither Davidson nor Bowman overcome the deficiencies of Fitz and Vitale, therefore, the rejection should be withdrawn because neither reference provides any teaching, suggestion or description of a fixation portion that is configured for implantation into an interior bone space of a mammalian vertebral body, as required by Applicant's claim 50, from which claim 53 depends indirectly.

For the foregoing reasons, Applicant requests that the rejection of claim 53 under 35 U.S.C. § 103(a) as being unpatentable over Fitz or Vitale in view of Davidson or Bowman be withdrawn.

### CONCLUSION

For the foregoing reasons, Applicant requests the Examiner allow claims 50-89 and advance the application to issuance.

Application No. 10/658,507  
Amendment dated November 13, 2006  
Reply to Office Action of August 10, 2006


### **FEE AUTHORIZATION**

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 29914-701.411).

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Respectfully submitted,

By:

  
Cecily Anne O'Regan  
Registration No. 37,448

**WILSON SONSINI GOODRICH & ROSATI**  
650 Page Mill Road  
Palo Alto, CA 94304-1050  
Direct Dial: (650) 849-3207  
**Customer No. 21971**